NORTH CAROLINA HIE DRAFT OPERATIONAL PLAN COMMENTS

Date	Name	Comment/Input
8/20/10	Beth Ferrell-Phillips – Greenville Pathology	1) 0.2 Background Page 7 *Statement of Expectations for NC HIE Workgroup Participants* Was this process ever made public as to make sure ALL parties were represented? Private Anatomic Laboratories are not in my opinion properly represented. 2) 0.4 Gap Filling Strategy Section 4.3 Page 53 last paragraph continued on Page54 A lot of the provider offices still receive paper reports that they scan an image into their system. ASP models of transmission are seen in a statistically observed amount of offices in the eastern part of the state because of cost for upstart. I don't know that I agree that "laboratory and care systems are rarely interoperable" because most provider offices require the laboratory to conform to their specifications instead of the other way around. Thus all the laboratories feeding results into their system are doing so in the same format. 3) 0.4 Gap Filling Strategy Section 4.3 Page 54 2nd paragraph An Anatomic Pathology only laboratory, or one limited in its clinical pathology testing, would never be able to be eligible to meet the Stage 1 meaningful use requirements, because they result in a verbiage format in anatomic pathology not a positive/negative or numerical format. 4)0.4 Gap Filling Strategy Section 4.3 Page 54 Laboratories housed outside of the state of North Carolina such as Quest and the out-of-state Urology and GI laboratories that have a significant presence in North Carolina provider's offices should also be considered. 5) 0.4 Gap Filling Strategy Section 4.3 Page 54 Gap Filling Strategies for Delivery and Receipt of Structured Lab Results Statute, Regulations, Policy When developing these standards, one must consider the uniqueness of the laboratory results being generated from Anatomic Pathology laboratories. The verbiage used by not only two different laboratories, but two different pathologists in the same laboratory for the same diagnosis is very individual. Things such as the terminology when they trained, where they trained, to what level of expertise they have with a certain specimen type, and grammar from varied language backgrounds can all be influences in making the verbiage used differ.

		6) 0.5 Governance Section 5.6 Page 64 Workgroups and advisory panels should include a variety of laboratories to include private anatomic laboratories, and should not be solely one laboratory represented (LabCorp***)*** 7) 0.6 Technical Infrastructure Section 6.5 Page 78 Figure 15 Anatomic pathology now routinely employs images also. 8) 0.6 Technical Infrastructure Page 78 3.3 Quality Reporting Provider or hospital reports quality measures to CMS or State Laboratories also report quality measures to CMS. 9) 0.6 Technical Infrastructure Section 6.7 Page 87 Vocabulary I believe LOINC should read "clinical" pathology results because anatomic pathology uses CPT-4 10) 0.9 Finance Section 9.6 Page 117 This is a very important point. Large laboratories would be very reluctant if it is a per usage basis. In the same manner, though, fees should be considered in a tiered manner so that the small independent laboratory is not paying what the larger ones are. 11) 0.10 Coordination Section 10.1 Page 120 Overview Your specialty societies should ALL be represented at the table; also there are associations such as ours (NC Pathology Managers Association) that would welcome a place at the table. 12) 0.10 Coordination Section 10.6 Page 129 Other States Referral testing is a significant market for other states that may not border North Carolina. These entities have electronic interchanges with our NC providers. 13) 0.13 Appendices beginning with Section 13.3 Page144 Although I respect LabCorp's active involvement in the process, and do not begrudge them a board seat, I am disappointed to see that all the positions I view as laboratory seats at the table have been filled with LabCorp individuals. No matter their level of expertise, I find it hard to believe that there are not equally qualified persons at Spectrum, Quest, hospital- owned laboratories, or one of the privately- owned pathology laboratories across the state. These smaller laboratories have as much to share, possibly more at stake, and represent specific challenges to this project. If you need laboratory names and/or contact information, the NC Pathology Managers Association would be happy to supply you with our membership listing.
8/20/10	Joseph Sholy – Wilmington	Although there are other concerns, the main issue is that the system design does not de-franchise small regional pathology and clinical laboratories from participating.

	Pathology	0.4 Gap filling Strategy Section 4.2, Page 53, 54 Integrating laboratory results into clinicians' systems faces a number of challenges. Even when transferred electronically, physicians often deal with laboratory results from a variety of sources that are transmitted by differing modalities, including facsimile, email, portal, and direct interfaces into EHRs. In addition, laboratory and care systems are rarely interoperable. While most laboratories use HL7 messages to send results, they use idiosyncratic codes to identify tests.15 Therefore, clinicians' systems cannot fully understand the results they receive which requires them to either adopt the producer's laboratory codes (which is difficult if they receive results from multiple sources), or map each result from a producer's code system to their internal code system. The difficulties outlined are due to the variety of physician practice EMR systems. Uniformity in EMR formats would easily be accommodated by laboratories. 0.5 Governance; Section 5.6, Page 64 Workgroups and advisory panels should be represented equally by national laboratories as well as local regional laboratories through local associations such as NC society of pathologists and not be limited to National laboratories.
8/21/10	Dr. Edward Ermini	This letter is a response/comment to the North Carolina Health Information Exchange Operational Plan Draft published August 18, 2010. Please be advised that these comments are my personal opinions, and are not known or endorsed by any organizations to which I am a member. There are several concerns I have with the whole process of Meaningful Use and Health Information Exchange as contained in ARRA/HITECH. Although I realize that these are federal laws, the North Carolina Health Information Exchange is an extension of the legislation, and the current proposal cannot be evaluated without taking these into consideration. For many years I have been an active advocate of Health Information Exchange as a tool and driver of Quality Improvement in Medicine. It is my belief that this tool should primarily be focused on assisting providers in delivering quality care at the point of service. Research and epidemiology are important components of Health Information Exchange, but are secondary to the goal of providing clinicians access to the important information necessary to make effective recommendations for patient care. The Meaningful Use Criteria required by the current administration do little to improve the delivery of care without a functioning health information exchange network, and require clinicians to gather much information that would not normally be contained in an office note. Collecting this information has traditionally been the responsibility of state agencies such as Health Departments and Federal Agencies

		(NIH, CDC etc), but has now been placed upon the providers. Health Information Exchange will make the job of insurance companies, health agencies, and researchers easier. However, it will drastically increase cost and administrative burdens for the providers who attempt to use it to provide care to their patients. Implementation of a certified system in a medical practice is a difficult enterprise for any provider in a small office, and it has become much more difficult in the last year. The numbers quoted for Electronic Health Record Adoption in North Carolina in this draft are incorrect (page 114). Currently, clinician adoption of the certified electronic record systems necessary to meet Meaningful Use Criteria is 0%. This is because there are no certified systems. There are no certified systems because the government has only recently been taking applications for certifying agencies. Although a small percentage of clinicians use some type of EMR system, all of these systems are now obsolete due to the provisions in ARRA/HITECH. It is unclear how many of these providers will upgrade their systems in order to comply with Meaningful Use. Early adopters of EMR have been penalized for purchasing systems prior to the Meaningful Use Criteria publication, and may not be willing to purchase new systems or allocate more financial resources for upgrades. Providers who have not yet adopted EMR will not be adequately reimbursed for the cost of purchase and implementation of certified systems, even if they do manage to qualify for Meaningful Use and receive federal incentives. Savings realized through efficiency in practices will be gobbled up by maintenance of systems and compliance with the regulations coming in Phase II and III of HITECH. It also appears that providers will have to implement ICD-10 and purchase biometric security devices for prescribing narcotics in order to qualify for future Medicare incentives under the later phases of HITECH. For those attempting to qualify under Medicaid, they must rely on matching state funds, which are unlikely to come from a state in fiscal difficulties. Providers in North Carolina have been slammed with a 9% Medicaid fee cut this year with more reimbursement decreases forecasted for the future. A 21% Medicare cut has been threatened, and commercial insurance companies continue to increase deductibles and co-pays while decreasing payments to physicians. Clinicians simply do not have the financial resources to purchase the systems necessary to make Health Information Exchange possible at this time On page 117 of the NCHIE proposal it is stated that financial sustainability for the network may be achieved by “usage fees” and “membership/subscription fees” which may be assessed to providers possibly now and surely in the future for “Value Added” services. I am strongly opposed to any additional costs being charged to clinicians at any time in order to make this network sustainable. I believe most physicians in the state will decline to participate when they realize there are fees attached to participation. Patients, researchers, payers, and government will benefit most from a health information network, and that is who should pay for it. I am also opposed to the “Opt-out” model proposed on page 96. The data that is being collected and stored under the meaningful use criteria contains demographic and personal information that could cause

		great financial and emotional harm if it got into the wrong hands. Not only should we consider the Opt-in model exclusively, but require patients to sign an informed consent form similar to the one we use for surgery that explains the risks of electronic health information transfer. Patients should know that the record contains their most personal health information, as well as demographic data and credit card numbers that could be used for identity theft if acquired by the wrong individual. Patients should also be informed that their information will be available on a system the can be accessed by hundreds of users in each of thousands of hospitals in the nation. Also, they should know that if their data is outsourced by insurance companies or researchers to offshore entities it will be outside the jurisdiction of the United States legal system. Finally, we should charge them a sustainability fee when they opt-in. I am also strongly opposed to any alterations and exclusions to the medical record. Once a patient opts in, every bit of clinical information should be available to every clinician allowed access to the record. It is the only way to preserve the patient-physician relationship while preventing dangerous omissions from the medical record. The patient should also have the option to place vital information in a place where it can be accessed in a "break glass" emergency situation. It is not necessary that this information include demographic and billing information. That can be obtained at a later time. This information should include drug lists, allergy information, ICD, and CPT codes. If they are not available from the clinician, they should be obtained from pharmacies and government/private payer databases, where they are currently stored. The quest for a functioning health information network is admirable. I feel we have attempted to do too much too soon, with too little. In the journey to provide patients with less expensive higher quality care, we have lost the perspective on what is important. Too many entities outside of the medical profession are seeking to peer into a record that should be a sacred trust between an individual and the physician they have entrusted with their life. The current proposal is unsustainable, unrealistic, and threatens to do much harm if implemented as proposed.
8/22/10	Joe Freddoso MCNC	1) The report lists the ARRA BTOP awards to NC as important to the HIE on pages 6, 47 and 48. The report really never relates why. I would suggest adding something at the beginning of section 3.3.j like this: In order for HIE related applications and services to perform with proper speed and reliability, a robust fiber optic based broadband infrastructure is required. This fiber infrastructure should interconnect all elements of the health care ecosystem within the State of North Carolina to an Intranet infrastructure and then through this Intranet infrastructure connections to the commercial Internet, advanced research networks and federal information repositories are provided. The health care ecosystem in this vernacular includes all places where care or examination is provided, information is stored, reimbursement is offered, medicine is disbursed:

		1) All in-state facilities that host repositories of healthcare information 2) DHHS 3) State and County public health facilities 4) Free clinics (county, local, non-profit) 5) Federal health facilities located in North Carolina 6) Hospitals - University, non-profit, publicly owned, privately owned 7) Practice offices 8) Insurance providers 9) Pharmacies Private sector and public sector networking technology providers must work together in order for such an infrastructure to be provided. The State of North Carolina has been aggressive and successful in pursuing federal broadband recovery funds through both the department of commerce's BTOP and department of Agriculture BIP funding. Currently in two rounds of funding North Carolina has received the following infrastructure awards that have great potential to assist in building a core HIE network infrastructure (NOTE: I WOULD ALSO USE THIS TABLE TO REPLACE THE BTOP/BIP award portions of the funding secured table on page 6--The HIE will not benefit much from the Charlotte Public Safety award for example).			
8/22/10	Joe Freddoso - MCNC	**Company Name**	**Award**	**Date**	**Purpose**
		MCNC	$28.2M	1/20/10	BTOP award to expand NCREN in rural SE and Western NC
		French Broad Electric	$1.8M	7/02/10	French Broad Electric Membership Corp will receive $1.8 million from the U.S. Department of Agriculture. Over 2,500 people stand to benefit from the provision of broadband internet access to Spring Creek, Laurel, Beech Glenn, and areas of Marshall and Mars Hill, North Carolina. Approximately 700 businesses and 6 community institutions also stand to benefit.
		Skyline Telephone	$29M	7/02/10	BIP-Skyline Telephone and SkyBest Communications will receive $29 million in broadband grants funds, and estimates that the project will create approximately 100 jobs upfront and help drive economic development in the community that creates jobs for years to come. Approximately 1,750 people, 600 businesses and 100

					community organizations stand to benefit from the expansion and provision of advanced fiber-to-the-home services via a fiber optic network in Alleghany and Ashe counties in northwestern North Carolina.
		Utopian Wireless Corporation	$460K	8/2/10	This $460,000 award to Utopian Wireless Corporation will bring WiMax infrastructure to rural communities in and around Riegelwood and will provide broadband access to underserved household and businesses. The Utopian project stands to benefit approximately 3,000 people, 450 businesses, and 30 other community institutions.
		Country Cablevision	$25.3M	8/2/10	The YMRB project, using this award of $25.3 million, will promote social and economic development in a rural, economically-distressed area of North Carolina by delivering critical digital services (TV, data and VOIP). More than 33,000 people, approximately 1,900 local businesses, and 120 community institutions stand to benefit from this improved service. Not only will this project create jobs upfront, it will help drive economic development in the community that creates jobs for years
		Atlantic Telephone Membership Coop	$16M	8/2/10	Through this award of $16 million, Columbus County ACCESS will provide an all Fiber-to-the-Premises (FTTP) network for high-capacity data, voice, and video services to critical community facilities and public safety entities. More than 8,700 people, approximately 270 local businesses and 35 community institutions stand to benefit from this improved service.
		Wilkes Telecommunications	$21.6M	8/2/10	This $21.6 million award to Wilkes will provide last-mile fiber optic high speed broadband, video, and voice services to

					underserved rural areas in Wilkes County. Wilkes Telecommunication's project stands to benefit approximately 8,500 people, 3,300 businesses, and 45 other community institutions. Wilkes estimates that this project will directly create at least 160 jobs upfront.
8/22/10	Joe Freddoso, MCNC	Lumbee Electric Power	$19.9M	8/2/10	This $19.9 million award to Lumbee River Electric Membership Corporation will provide an advance Fiber-to- the-Home (FTTH) broadband services via a high speed fiber optic network designed for speed up to 100 megabytes per second to end users in our rural proposed funded service area. Lumbee River Electric's project stands to benefit approximately 27,000 people, 1,600 businesses, and 100 other community institutions.
		Yadkin Valley Telephone	$21M	8/18/10	BIP-This approximately $21 million award, will allow Yadkin Valley Telephone Membership Corporation to offer a diverse Fiber-To-The-Home (FTTH) network to areas of six counties in the Piedmont area of western North Carolina. Approximately 12,803 people stand to benefit, as do roughly 606 businesses and 56 community institutions.
		MCNC	$75.8M	8/18/10	BTOP-This approximately $75.8 million award will allow MCNC to offer affordable middle-mile broadband service in 69 of the most economically disadvantaged rural counties along the northern and southern borders of North Carolina. The project plans to directly connect 170 community institutions to broadband. As many as 5.1 million stand to benefit as do 160,000 businesses.
		Total	$249.1M		Still about $500M to be obligated
		2) May want to consider adding this working when you discuss the NCTN if Dave Kirby and Steve Cline			

		are comfortable adding this to 3.3i (page 46): MCNC is working closely with the HIE Board and specifically the Clinical/Technical Workgroup regarding plans to increase broadband capacity in NC. MCNC has been very successful in securing funding to build connectivity and capacity. The extension of middle mile fiber to more communities will allow local ("last mile") internet service providers to provide broadband capacity at a more favorable cost to individual healthcare facilities. In January 2010, MCNC received federal funding to expand their middle mile network into 37 counties in the west and southeastern portion of the State. In addition, MCNC has applied for Federal recovery to build middle mile fiber and also direct fiber to select key community anchor institutions in 69 rural counties. This will likely meet the last mile needs of some major non-profit and university hospitals and bring the middle mile closer health care facilities throughout the State. MCNC will receive word on BTOP 2 funding the week of August 16th. Finally, note also that both the North Carolina Office of Information Technology Services (ITS) and MCNC have a long history of working with last mile providers in procuring last mile services to education facilities and has offered to help with this aspect for healthcare facilities and if needed physician offices. ITS and MCNC recently collaborated on and won a bid to connect County Health Agencies and County Free Clinics to the ITS and MCNC backbones. These backbones peer seamlessly with one another, serve as resilient back-up to one another and ITS and MCNC collaboration is at a very high level when it comes to providing backbone network services to the healthcare sector. The two entities are planning on another cooperative bid to provide backbone networks services to the non-profit and university hospitals in the State.
8/23/10	Jeffrey Harris & CommWell Health Staff	We would like congratulate the dedicated team that has organized so quickly to form the North Carolina Healthcare Information Exchange workgroup and your product. We have been asked to go on record with some feedback regarding the document and have expended effort this weekend to familiarize ourselves with its components and understanding of how NCHIE intends to proceed. Please keep in mind that our comments arise from the context of our eight-site FQHC which has made significant capital investment in electronic health and dental records, a hosting environment and support organizations to attend to the care and feeding of our technology. As you know, our sector of the industry focuses on serving the under-served and under-insured. In the last six years we have been fortunate to receive several grants that allowed for the adoption of health information technology. Unfortunately, our experience indicates that the technology acquisition is a mere fraction of the organizational burden associated with the implementation, design of functional interfaces that address business needs and hopefully provide a culture changing influence which increases patient

		safety and organizational efficiency. The overall intent –we hope is that we will have more time to focus on our core competencies (acute care and chronic disease management) and be informed with a more complete bio-psycho-social data set. **General Feedback: Market Timing** As an FQHC we are held accountable for patient access and the overall population health of the critical-access zone defined by our catchment area. Our organization delivers medical, dental and behavioral health services so we feel blessed to offer a complete set of patient-centered, integrated services. To that end, the NCHIE impacts virtually every aspect of our daily business wherein it addresses Electronic Medical Records, Practice Management Systems, Case Management Systems, Dental Record Systems, Behavioral Health Systems, Business Intelligence subsystems used to provide granting agency reports and accurately project the needs of our community; HL-7 interfaces and ETL processes. We have found it difficult at best to organize our sentinel data sets and encourage numerous vendors to work as part of our team which is converging on standard use cases for our clinical procedures and businesses. The current provider market is under siege from numerous vendors all of whom promise to meet meaningful use criteria. What is never said is that vendors can only support meaningful use with their products: It is the organization that must adopt the workflows and data flows necessary to prove meaningful use. With the first payments for meaningful use occurring in 2011 through physician attestation we sense that many new implementations and revisions to existing systems are forthcoming in the next 12 months. The timeline for technology acquisition seems to be ahead of the planning and design components for the State's HIE. In this we are fearful. Several of us in our organization have worked in the commercial sector and are aware of the propensity of vendors to implement beta product which is constantly refined by re-versioning the systems of early and mid-stage adopters. This place's 2011 physician adopters at risk with regard to integration with the NCHIE since there are only five or so Authorized Community Exchanges of which none are completely implemented. **NCHIE BOD** As we reviewed your document and studied the core components of the board and workgroup we noticed an apparent absence of vendors with the exception of IBM, Labcorp and Kerr Drug. The board is wonderfully comprised of experts in medicine, clinical affairs and population health and we suppose NCHICA provided strong value in terms of technical assistance relating to the state of the market from an engineering perspective. Unfortunately, the technical standards for message exchange and message format: where much better than last year; are still incomplete. In fact, it is not uncommon to see vendors using various HL-7 message segments to transmit data not intended for the segment thereby violating the original intent of the standard. Ultimately, the burden of troubleshooting message errors falls on us providers as we detect a problem in our business process whether it is as simple as unexplainable variations in reporting or as serious as a loss of revenue or patient endangerment.

		We would like to suggest that the Board (page 54) consider forming a group of vendors now targeting NC e.g. GE, e-Clinical Works, Greenway, Henry Schein, All Scripts and others. It may sound counter-intuitive that a vendor would freely share their product pipeline, but we have recently found the contrary to be true and your group represents a much larger potential customer base. Hopefully this will give your staff some for-sight into what is likely to be adopted here in our State and perhaps create value for the providers planning to adopt e-HRs along with the REC. Furthermore, your proposed infrastructure plans to use a service oriented architecture with some early value adds such as TLS security, a probabilistic patient matching function, master facilities and provider indexes and the rendering of e-Prescribing, Lab Results and Summary Care Records. **Business and Technical Standards pages 89-90:** The fact that you are offering the eRx, Lab and Summary records implies that you will be negotiating access with sure-scripts/RxHub, major labs such as Quest and Lab Corp who already provide a portal for physicians and care summary material (we presume CCD/CCR) which will be coming from various EHRs. Your future value added suggestions include medication reconciliation and clinical decision support as well as many other solutions such as access to aggregated data. We applaud this vision. Our question relates to the fact that numerous commercial products are providing this functionality already. In speaking with John Halamka and others we are finding that many organizations are moving toward hosted solutions or virtualized private clouds which will offer these functions. Are you proposing that the value added services provided by NCHIE replace the functions in existing systems or are you offering products that will assist physicians to adopt much needed technology? If this is the case, will you standardize items like medication reconciliation processes with commercial products in order to provide a consistency of experience for physicians who migrate between clinics (a frequent case in our world)?

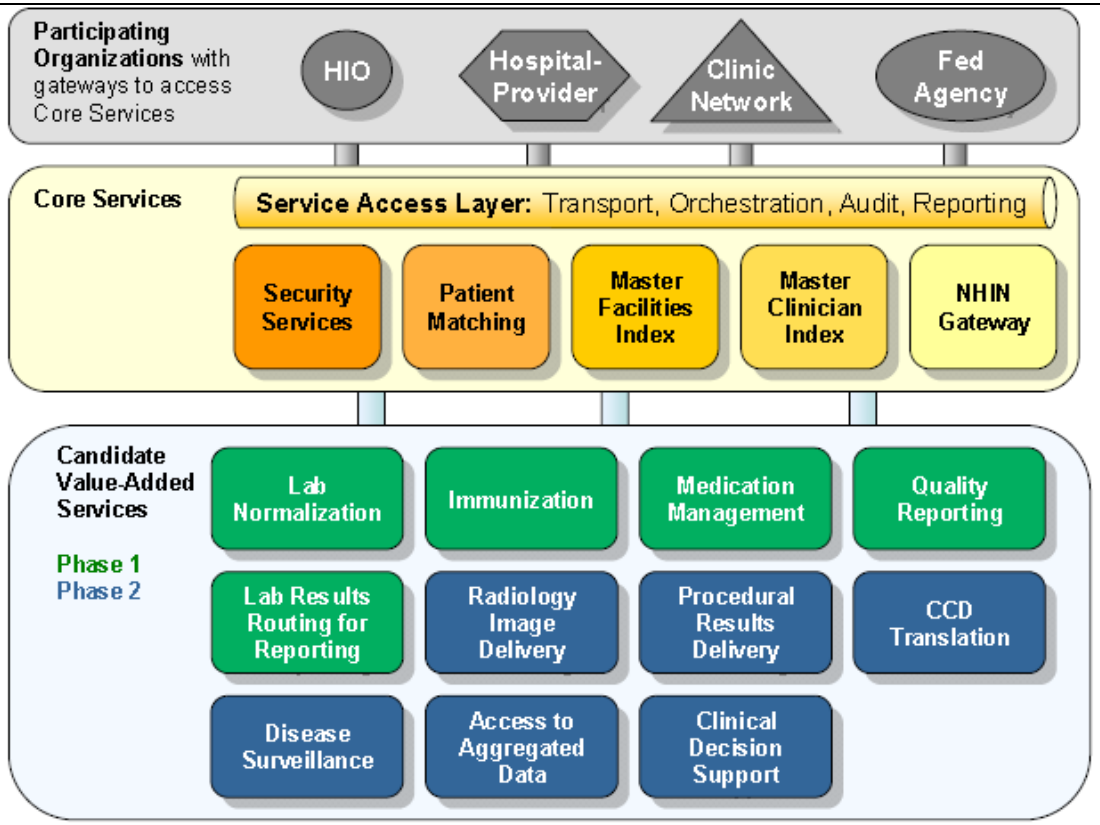

Figure 17. Proposed Core Services and Phased Implementation of Value-Added Services

The architecture above does not include assistance with providing Hosted Clinical Systems. This is a much needed service as the majority of Community Health Centers –if they employ HIT- find themselves with sizeable budgets for Network Administration, have deployed thick client-server models requiring the employment of service technicians and network administrative staff and seldom have a well thought out data recovery and business continuity plan. For example: Our organization supports 240 users through an ISP provided fiber ring with encrypted VPN linking our network. Unfortunately, our data/application center is in-house and we have no provision for emergency power other than UPS. With no generator, one single lightening strike can bring eight clinics to a close within thirty minutes until the transition to paper. Thankfully we have offsite, redundant data backup. One roll of the NCHIE could be to assure that we have secure hosting facilities, perhaps virtualization and assistance with the development of business continuity planning through the REC. Sequestering funds to assist with these needs might foster adoption of a sustainable infrastructure.

Another process noted in the Candidate Value Added Services section is Quality Reporting. Presently we are aware of the quality reporting standards of CCNC (who nicely compiles national standards); The Bureau of Primary Health Care UDS report, the commercial BTE products for disease centric and medical home recognition, the NQF suggestions etc.

Keep in mind that a clinic such as ours receives a large proportion of its operating revenue from grants, Medicaid, Commercial Payers and sliding fee self-pay clients. To appease the various granting authorities we are subjected to numerous operational and often redundant clinical reporting and business report requirements. For example: Ryan White programs require that we use their web-hosted care coordination system which means we either duplicate data entry (increasing the possibility of error) or build interfaces using crude tools provided by HRSA (MS Access conversion and creation of .csv files). This is but one of many activities that we perform that are not direct care oriented and require the employment of costly staff thereby driving us further from our vision of efficient , high value population management.

We see a role for the NCHIE in assisting us to negotiate meaningful meta-data definitions with Federal, State and Private quality monitoring initiatives. For instance, the codification of message standards for reporting statistics , clinical indicators and the use of standard technologies would allow NCHIE to receive direct feeds from our clinics either through real time or ETL processes. The NCHIE could then provide a business intelligence application (web native) giving persons in Participating Organizations the capacity to review their data, compare and contrast with peers, publish and perform various OLAP functions.

Your document specifies $45M coming to our state in the following table on page 4:

ARRA Program	Awardee	Amount
State HIE Cooperative Agreement Program	North Carolina HIE	$12.9 million
State Medicaid Planning	State Medicaid Agency	$ 2.3 million
Regional Extension Center Cooperative Agreement Program	North Carolina Area Health Education Centers Program (at UNC Chapel Hill)	$13.9 million
Beacon Community	Southern Piedmont Community Care Plan	$15.9 million

It appears that the Regional Extension Center Project when fully staffed with 40 FTE s will have a provider to technical specialist ratio of 87/1. The cost for these services will be approximately $4000 per

		physician; and if each of the targeted 3465 physicians meets MU Medicaid criteria it will translate into $221M. We would like to know how the 3465 physicians were selected as the document states that they are “high priority”. We hope the REC is successful and imagine that they will do a wonderful job. It is our opinion that the ratios of physicians to support technicians are high if the physicians are small private practice organizations with little training in process change, data migration and the business controls necessary to ensure that everything is working properly. We would hope that some form of centralized training would be provided in various regions and that the REC is able to bring select vendors to the table to provide additional training and monitoring processes throughout implementation and in future years for monitoring purposes. **Additional detail and questions:** **3.2 Qualified Organizations** We note that to quality; a participating organization is to aggregate providers for purposes of connectivity to the HIE. We assume that our eight clinics of Dentists, Physicians and Mid-Levels would suffice. We would like assistance politically with hospital integration in our service area especially where it comes to IP facilities who service large Medicaid populations for non-urgent ambulatory sensitive conditions. Statewide Policy Adherence: We assume that this applies to NCHIE only. If other policies are considered please clarify. For example: If the State determines that a specific EBG should be deployed we would want assistance with our vendor to set up our records and alert systems to embed any clinical rules arising from the States mandate. Once again, if the prescription fills status and other RxHub features as well as clinical summary records are to be passed through the NCHIE we would need to know how the PHI is handled. IE: is it stored in a repository with identifying information? How is patient consent handled? Qualified organizations are to be consumer oriented with their policies and activities. Does the NCHIE envision providing a Patient Portal/Personal Health Record? If so, has NCHIE considered patients designating their own entities and agents to provide access to their records thereby placing the burden of approving record access with the patient? One notable technology would be to deploy MS Health Vault with contracts to update the Vault with State data as allowed by the patient. Is the NCHIE currently negotiating for access to Sure Scripts and RxHub? If so, how do these contracts work and is it possible to get State sponsoring for an applying qualified organization to offset the $20 per

		provider month service fee? Is it likely that CCR/CCD will be used and a standard version/code structure be negotiated with vendors of e-HR technologies in NC? Will being a Qualified Organization be a prerequisite requirement for incentive payments for meaningful use under Medicaid? It is noted that AHEC is developing a preferred provider list: When can we expect the results of your due diligence? How do we access or who do we contact regarding the NC e-HR Loan Fund through HWTF? NCHEX It appears that NCHEX is providing a full service offering including e-HR light with interfaces to Emergency Department records, ADT patient admission information, labs, dictation, pharmacy, etc. Providers have access to med hx. Provider hx. Procedure hx. Allergies, labs, summary data for last 36 hours and discharge summaries. These data are invaluable to primary care. Will this service be for hospital based physicians only or can providers in the catchment area such as FQHCs and specialists have access to these data? What would the format of the data be? CHEX also provides public health reporting data. May we inquire as to what data will be available? Will they be de-identified or will we have access to the data through the NCHIE patient matching engine with consent. NCHEX speaks to clinical alert capabilities: Are these alerts at the medication/medication level, medication allergy level, medication condition level, lab result level etc? It appears that NCHEX is in partnership with 57 hospital owned physician practices. NCMS is also working to identify independent physician practices and additional stakeholders such as NCDHHS Public Health and CCNC. **We would like to go on record by stating that we are extremely interested in participating in the project with special interests in Johnston County Health and Betsy Johnston** **Memorial Hospitals.** 3.2 Continued: It is further stated that Qualified Organizations: Provide electronic collection of 646 Chronic Disease measures. Will interfaces be provided or are we expected to create our own ETL processes.

		Development of policy guidelines and data collection for publication is a requirement. Have any guidelines been developed yet? How will these synchronize with the requirements of HRSA. PQRI, BTE, UDS and IPIP. We would like to suggest that all of the organizations collaborate to establish a uniform set and instructions for patient removal from the sample and calculations for numerators and denominators. Otherwise you are presenting another potential non-patient care task for the thinly capitalized safety net. One goal is to improve the coordination of care: how will this be measured? **Community Care of NC:** It appears that CCNC is performing audits of CCNC physicians and collecting data from the State's EDI ims system. These data are said to be housed in the CCNC Informatics Center. The data contain patient demographics, pharmacy and medical claim information on Medicaid, Health Net and Health Choice members. It is stated that the dataset includes 2 million Medicaid recipients, yet CCNC represents 970,000 recipients. Wherein CCNC is housing information that could be crucial to treatment at the point of care we would like to know if we can also have access to these data for registrants at our clinic. It appears that two web-native applications: CMIS and Pharmacy Home render important medical history to the case managers and primary care clinicians on patients receiving care in the Medicaid provider and Health Net networks. Wherein FQHC's also treat these populations we would like to request access to these data to facilitate a more thorough knowledge of the patients we are treating and to ensure that we assign the patients to the correct PCP. **Final Comments:** CommWell Health (formerly known as TriCounty Community Health Council) serves over 30000 users across multiple counties. Our patients are comprised of uninsured, Medicaid, Medicare, Industrial Self Insured Clients and others e.g. Migrant Health Workers. We employ pediatricians, Infectious Disease physicians, Internists, Family Practitioners, Mid level practitioners, technical and nursing staff. We manage over 40 individual grants, have a wonderful reputation with our LME and SAMHSA and are members of the CSP program. Our operating hours cover six days per week and we have clinical staff on call. We hope you take the aforementioned as helpful suggestions, many of which we are sure you have already considered. We stand behind you in your project and can be called upon for assistance as needed.
8/23/10	Rod Baird Geriatric Practice Mgt., Inc,	We reviewed your recently published plan (to the extent available time permitted). Our review was performed from the perspective of the clinicians we represent – more than 50 Physicians & Physician Extenders working in 4 medical groups that serve over 100 North Carolina Nursing Facilities & Rest Homes. In the course of a year, these clinicians treat ~ 10,000 unduplicated patients. Nearly all of the clinicians have a primary care specialty (IM or FP).

		Two of the four groups are active participants in the 646 Demonstration project (**North Carolina Medicare 646 Waiver -Page 39 of your plan).** All of our clinicians use some form of Electronic Medical record; some use a CCHIT certified system, others a less vigorous system based on dictation/transcription – but incorporating structured data. All data is available for sharing via secured electronic interchanges. We scanned your plan to determine the extent to which it supports strategies to both permit & encourage Physicians & Extenders working in the LTC setting to access data via the HIE(s) you describe. We also noted your discussion about possible legal prohibitions against the sharing of patient records (by Nursing Homes) at **13.6 North Carolina Legal/Policy Workgroup Legal Scan Documents** We encourage you to devote some degree of attention to the benefits to the State (particularly DMA) from having Nursing Home Patient information incorporated into an EHR used by LTC physicians. This is a significant problem for those physicians – they are the individual responsible for ordering all Lab & Pharmacy services for LTC facility residents. However, the LTC facility is the entity which actually selects the Lab and Pharmacy provider(s) and transmits the physician's order. Since few LTC facilities have an accessible EHR, physicians have to place their initial orders verbally or in writing. Further, the facility is capable of changing Lab & Pharmacy providers without the ordering physician's knowledge. Identifying a (compliant) way to incorporate the results of these orders into the Physician's EHR is necessary if those Physicians are to achieve 'Meaningful Use'. Since a key objective of the 646 program is to have electronic records, the HIE plan should address this issue. Further, consider that a very considerable amount of medical care in the LTC setting is provided by Nurse Practitioners. Nurse Practitioners aren't able to participate in the Medicare EHR incentive program (they aren't listed as eligible providers). However, the Medicaid EHR incentive program does cover Nurse Practitioners as Eligible Providers. Consequently, it is critical for the State to create avenues that will both permit and encourage the clinicians who perform the Medical Management of the patients who consume more than 1/3 of the Medicaid Budget to adapt and use EHR. Plotting an avenue for this to occur can begin with the NC HIE operational plan. While this is only a small part of the overall health delivery system, it has the potential to yield immediate savings to both Medicare & Medicaid via improved decision making (LTC residents are some of the most expensive individually identifiable beneficiaries for both Medicare & Medicaid).
8/23/10	Richard Furr,	Please find SAFE-BioPharma Association comments on the North Carolina Health Information Exchange

	SAFE-BioPharma Association	Draft Operational Plan keyed as requested in the forwarding e-mail. I appreciate the opportunity, on behalf of SAFE-BioPharma to review and comment on this draft. Overall impression: This is a well developed thoughtful plan that obviously was put together by a strong team and lays the groundwork for a solid effort. There do not appear to be any glaring omissions nor does there appear to be any bias toward any specific technical approach. Specific comments follow: Section 3.3, page 15, bullet list in first paragraph, either add to the fourth bullet or add a new bullet to include "Credential Service Providers (CSP) and Identity Service Providers (IdP) that provide identity credentials and identity management services to the healthcare industry." Section 4.2, Page 50. In the discussion of e-Prescribing (or in other sections such which also address e-Prescribing) it may be useful to include a reference to the new Drug Enforcement Agency rule for e-Prescribing of controlled substances. This rule requires prescribers to obtain and use x.509 digital identity certificates which are protected by a cryptographically hardened Pertinent sections of the rule are included below. CFR Parts 1300, 1304, 1306, 1311 1311.105 Requirements for obtaining an authentication credential – Individual practitioners. (a) An individual practitioner must obtain a two-factor authentication credential from one of the following: 301: (1) A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800-63-1 as incorporated by reference in § 1311.08. (2) For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above. (b) The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority. (c) The credential service provider or certification authority must issue the authentication credential using two channels (e.g., e-mail, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the practitioner has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two pieces of information used to

		generate or activate the authentication credential using two channels. 1311.115 Additional requirements for two-factor authentication. (a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors: (1) Something only the practitioner knows, such as a password or response to a challenge question. (2) Something the practitioner is, biometric data such as a fingerprint or iris scan. (3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access. (b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140-2 Security Level 1, as incorporated by reference in § 1311.08, for cryptographic modules or one-time-password devices. Section 6.5, page 79, Core Services, para 5, first sentence. Will the specific method of clinician authentication, i.e., type of identity credential used and protection mechanism for the credential be discussed in on-going work? The Office of the National Coordinator for Health IT NHIN Direct Security and Trust Working Group, on Jun 3, 2010, issued a consensus Proposal which recommended the use of X.509 digital certificates for identity management in healthcare. In Section 2.5 of the referenced document, the proposal states: 2.5 Sender identification. NHIN Direct messages must be reliably linked to the public certificates possessed by the sender, through standard digital signatures or other means that match the certificate subject to the sender's address or health domain. This reference to digital signatures clearly implies a PKI based certificate and most likely operating at a Level 3 assurance level as defined by OMB Circular 04-04 and NIST Special Publication 800-63. In the Federal Register of July 28, 2010, the Secretary of HHS promulgated the final rule on the certification standard for EHRs. Included in this rule at Section 170.302t is the following: Meaningful use Stage 1 objective Meaningful use Stage 1 measure Certification criterion Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process. Interim Final Rule Text: (1) Local. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

		(2) Cross network. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in § 170.210(d). Final Rule Text: *§ 170.302(t). Authentication.* Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. Section 6.5, pg 80, Security Services, last line. Does the inclusion of the phrase "authentication of participating entities and certificate authority allow for, or suggest, the use of PKI based digital identity credentials? Section 6.5, Pg 81-86, general comment. Would the plan consider the central management of digital identities as a value added service? Such a service could be offered as a third party hosted service that would not require the implementation of a State run offering with the attendant implementation and operational costs. Digital identities are cited because of the higher level of assurance and strength of identity proofing to ensure the user of such an identity is actually who they purport to be. Such a service could also establish a high level of assurance trust framework for the protection of personally identifiable health information. Section 6.6., page 86, Alignment with NHIN: Refer again to the previously cited Consensus Proposal from the NHIN Direct Implementation Working Group, Security and Privacy subgroup. Section 6.7, pg 87, Privacy and Security, para 1 – Compliant with the aforementioned Consensus Proposal. Section 6.7, pg 87, Privacy and Security, para 3 – Due to security issues with the SHA-1 algorithm, i.e., it is not a secure as it once was, NIST is now moving to SHA-256. In fact, digital certificates used by the Federal and cross certified bridges are required to move to SAH-256 early in 2011. May want to consider this as the plan moves ahead. Pg 103, Section 7.6a, 3rd para, Authorization and pg 105□106 □ Authentication Would it be appropriate to include some discussion of a risk based approach using the principles in OMB Circular M□04□04? Although the Circular was originally developed for Federal Agencies, it has become the more or less de facto guidance document for analysis of level of assurance requirements. In addition, NIST Special Publication 800□63 includes very useful guidance for identity proofing at the four levels of assurance and is widely used as the definitive guidance document. Thanks again for the opportunity to review and comment.
8/24/10	Dr. Joy F. Reed, DHHS, Health	I have reviewed the NC Health Information Exchange Operational Plan and found it to provide an excellent overall plan for moving forward. Below are my specific concerns about the draft document:

	Information Systems	• On page 16, the term "EHR" is used when describing what exists in practice today; this term needs to be defined and the difference between EHR and EMR delineated; what is in use in practice currently are EMRs (electronic versions of the old paper record) with no option for the individual accessing his/her own records. • On page 45, the information on HIS is outdated. At a minimum, the 2nd sentence needs to be changed to read: "The rollout of this system will be completed by the middle of September, 2010." • On page 65, since consumers have a very real "financial stake" in the healthcare system, does this mean that their salary does not come from healthcare? • Although the 85 local health departments are listed on page 13, they are not included on pages 112-113 and there is no recognition of their critical role in serving the uninsured, underinsured and Medicaid populations, some of the most vulnerable populations in our state. • Also on page 112, as well as on page 54, there is no mention of the State Laboratory for Public Health and its new IT system, STARLIMS, is not included in the document.
8/24/10	Daphne Lyon Office of Economic Recovery and Investment	<u>Pages 11-12. Section 3.1 Overview</u> Narrative discusses the four approaches considered, almost as a chronological event analyzing the pros and cons of each approach before concluding one of the four is the best. Consider a crisper, more direct presentation using the style of "The Board recommends [Approach Y] for these reasons" Followed by, " the Board also considered [Approaches X and Z], but rejected them for these reasons…" In this manner the reader gets up front what is planned, and need only follow the thread of what was rejected, and why. if it suits the purpose of the reader. <u>Pages 70-76. Section 6.3 Technical Approach</u> Similar comments as above. Narrative discusses the four approaches considered, almost as a chronological event analyzing the pros and cons of each approach before concluding one of the four is the best. Consider a crisper, more direct presentation using the style of "The Board recommended [Approach Y] for these reasons" Followed by, " the Board also considered [Approaches X and Z], but rejected them for these reasons…" In this manner the reader gets up front what is planned, and need only follow the thread of what was rejected, and why, if it suits the purpose of the reader. <u>Page 41. North Carolina Immunization Registry (NCIR)</u> The description of the NCIR implies a fully functioning automated, interoperable system. However, a recently submitted grant application for ARRA funding paints a much different picture of the NCIR. Some direct quotes from that application (emphasis added): "The objective of this project is to provide an interface that ***will*** enable … (EMR) … to send as well as receive ... This ***will*** enable … a complete immunization record ..."; "…providers could only report using paper-based systems.."; "Interoperability has been proposed for several years … many barriers have presented themselves…" Please confirm accuracy of presentation in this Plan.

		Page 45. Health Information Systems for NC Public Health Agencies (HIS) The Plan contains the phrase, "It is intended to rollout in late 2008 to early 2009" Update or omit. Page 109. Section 8.5 Next Steps The third bullet confirms the intent to pursue two pathways regarding patient consent. The challenges of pursuing any one solution are well explained, but what is not explained is how to operationalize the two approaches. Will redundant security operations be developed, or will the Board build the security using Pathway One, with current law, and modify should laws change. The final answer on any legislative changes likely won't be known by the time RFPs are issued for system build out under the proposed schedule. Page 113. EHR Adoption EMR us used in the first paragraph. Does EMR=EHR? If yes, use EHR; if no, explain difference. Page 116. Revenue Mechanisms The last sentence of the first bullet (Assessments) refers to "those benefiting from the exchange". Who do you mean? All citizens will benefit. So, do you mean "those who save money"? Well in fact, that would be only payers, including employers (as noted in the last bullet in this section). Perhaps "those benefiting" could be more precisely defined. If that definition does turn out to be payers, then what is the difference in the first bullet and the last bullet (Cost Saving/Sharing)? Page 118. Controls and Reporting Who from the Office of Recovery is providing this information? I am the primary contact for OERI and I have received no specific request. Should I be preparing something?
8/24/10	Annette DuBard NC Community Care Networks, Inc.	I have reviewed the NC Statewide HIE OPERATIONAL PLAN DRAFT dated August 18, 2010, and am sending along factual corrections for two areas (see below). My complements on an oustanding draft operational plan. Proposed corrections: 1. Page 32, 1st paragraph under CCNC. Updated figures for last sentence would be: "….physicians in more than 1,400 practices across North Carolina, serving over 1 million Medicaid and NC Health Choice for Children enrollees." 2. Page 37. The information about the Informatics Center appears to have been truncated, with one section repeated. The full description of IC applications for this section would be: **Case Management Information System (CMIS)** : CMIS is a user-built, patient-centric, electronic record of care management activities used by CCNC care

		managers since 2001, with over 1,000 active users statewide. CMIS contains demographic data and claims data on over 2 million Medicaid recipients, over 1 million of whom are currently enrolled with a practice in a CCNC network. CMIS also contains enrollment, eligibility and case management services for HealthNet projects across the state, which are regional collaboratives for the care of the uninsured, currently serving 12,500 enrolled individuals. Patients enrolled in Medicaid, Health Choice and HealthNet all reap the benefits of the continuity of care provided by CMIS, which maintains a health record and single care plan that stays with the patient as he or she moves from one area of the state to another, or across eligibility programs. CMIS contains standardized health assessment and screening tools, disease management and health coaching modules, and workflow management features. **Pharmacy Home**: The Pharmacy Home Project was created to address the need for aggregating information on drug use and translating it to the network pharmacist, case manager and primary care provider in a manner best suiting their care delivery needs. To accomplish this charge, the system was set up to provide both: 1) a patient level profile and medication history for point-of-care activities as well as 2) a population-based reports system to identify patients that may benefit from pharmaceutical care delivery via pharmacists, case managers and PCPs in the medical home. The Pharmacy Home drug use information database is used both prospectively (for identification of care gaps and problem alerts, targeting of at-risk patients, and development of the pharmaceutical care plan) and retrospectively (for continuous quality improvement and program evaluation). **Quality Measurement and Feedback chart audit system**: NCCCN conducts over 26,000 medical record reviews in over 1250 primary care practices statewide on an annual basis, to abstract medical record data pertaining to quality of care measures for asthma, diabetes, hypertension, heart failure, and ischemic vascular disease. Medicaid claims data is used to generate a random sample of eligible patients, and to pre-populate audit tool elements according to an individual's identified chronic conditions. Secure client-server software allows users to work offline when Internet access is not available in the clinic location. When access to Internet is available, the system automatically synchronizes data with the server. Data is fully encrypted offline and in transit. Data sent to the server automatically updates a variety of process, progress, and analysis reports. Practices and CCNC networks have immediate access to chart review results, with local, state, and national comparative benchmarks, through a secure web portal. **Informatics Center Reports Site**: NCCCN creates patient-, practice-, county-, and network-level reports related to population management, case management/case identification and quality of care/performance measurement through a secure web portal and report distribution system. **Provider Portal** :

		NCCCN released a Provider Portal in August 2010, which allows secure web-based query access to the health record of NC Medicaid recipients, by treating providers involved in CCNC quality initiatives. The portal provides medical home and care team contact information, medication fill history and current med regimen (with indication of adherence and therapy gaps); clinical care alerts for point-of-care decision support; and visit history including inpatient, ED, office visits, imaging, DME supplies. Medical home providers have direct access to cost, utilization, and quality, and care gap reporting for their patient population to assist with population management. The portal also provides access to a comprehensive resource of low-literacy patient education materials and multilingual medication counseling tools.
8/25/10	Dr. Dave Tayloe, Past President, American Academy of Pediatrics	I have read the first 139 pages. I understand all of this except the Clinical/Technical Workgroup part. May need to dumb that down a little more. Only other suggestion is to clearly state that AHEC is the Regional Extension Center in section 10.2 on pp. 122-123. Would also create an extensive list of acronyms with definitions; there are still acronyms within the report that I cannot decipher.
8/25/10	Donald E. Horton, Jr. - LabCorp	<u>Section 4.3, Electronic Delivery and Receipt of Structured Lab Results, pp. 53-55</u> <u>Section 6.5, Statewide Core and Value-Added Services, pp. 81, 86</u> <u>Section 6.7, Approach to Implementing Standards and Certification, p. 87</u> The following comment relates to each of the sections listed above. The draft operational plan acknowledges that integrating laboratory results into clinicians' systems is challenging due to the lack of interoperability between systems, due in part to the use of idiosyncratic codes by labs to identify tests (pp. 53-54). As a gap filling strategy for delivery and receipt of structured lab results, the draft operational plan proposes that NC HIE will conduct a cost-benefit assessment of a statewide Value-Added Service that transforms lab result messages to conform to the format, coding and transport requirements of the receiving EHR or public health agency and a component to route and transform laboratory orders as well as results (p. 55). The Clinical and Technical Operations Workgroup identified a list of candidate services to be offered as hosted shared services, including "lab normalization", described as a service to transform laboratory result messages to conform to the format, coding, and transport requirements of the receiving EHR or public health agency, in addition to vocabulary services, including access to or mapping of LOINC and SNOMED (p. 81). Lab orders were not specifically referenced in this description of the service. The Workgroup recommended the inclusion of this lab normalization service in Phase 1 of the NC HIE (p. 86). The draft operational plan proposes that the North Carolina State Health IT Coordinator will provide leadership in establishing statewide standards and requirements for HIE based on a number of national standards, including the HL7 2.5.x messaging standard for lab result delivery and LOINC for lab

		results (p. 87). However, the plan does not acknowledge the difficulties associated with standardizing the use of LOINC among laboratories for result reporting, which is itself subject to variability, or propose a plan to address that issue. Further, the plan does not acknowledge that no universal standard order code set applicable to laboratory test orders currently exists, or that use of other existing vocabularies for that purpose would be extremely complex if possible at all, and fails to propose a plan to address these issues. Lab normalization is a worthy goal that would bring value to all participants in the NC HIE, but its realization is dependent upon more code standardization than the draft operational plan has addressed. Section 5.4, Bylaws, Nomination Process for Future Board Members, pp. 61-62 The proposed nomination process for future members of the Board of Directors of the North Carolina Health Information Exchange (NC HIE) does not adequately provide for representation of, or accountability to, members or participants in the exchange, who would appear to have no direct vote for members of the Board. Further, the power proposed to be given to the Governor to approve or reject Board nominees undermines the independence of NC HIE as an entity separate from the State of North Carolina. While we agree that the Governor should play an active role in the overall governance of the organization, the "commitment to operating as a true public-private partnership" does not require, and in our view is in fact inconsistent with, complete control of the membership of the Board by the Governor, which the right to approve or reject all Board nominees would provide. The nomination process for future Board members should include some dedicated seats for gubernatorial appointees, but to achieve a true public-private partnership, members should have the right to elect at least an equal number of Board members who are independent of the Governor or other agents of the State. Section 5.4, Bylaws, Amendments, p. 63 We respectfully disagree that it is in the spirit of the public-private organization to require the Governor's prior approval for any changes to the bylaws pertaining to the mission of the organization; nomination, approval and election of directors; transparency; and conflicts of interest. While the Governor should always be fairly represented on the Board, the independence of the NC HIE as a separate entity from the State of North Carolina can only be secured when the State does not dictate the fundamental elements of its existence. Therefore, the only bylaw provisions that should not be subject to change without the Governor's approval are those that establish dedicated seats for State officials, as referenced in Section 5.5. Section 5.5, Authority and Involvement of the State, p. 63 We agree that the State has a non-delegable role as the steward of State assets and the protector of the public interest, and that it will be essential to maintain the integrity of the multi-stakeholder collaborative process in setting policy for the Statewide HIE; however, it does not follow, as suggested in

		this section, that there must be specific provisions in the Articles of Incorporation and bylaws that may not be altered, amended, or repealed without the Governor's prior approval (other than the establishment of certain dedicated seats on the Board for State officials to ensure fair representation, as referenced in this section). The State can and should exercise its oversight role through the enactment and enforcement of laws applicable to health information exchange in North Carolina and through participation in the NC HIE. However, the State can and should do so without controlling the operations of the NC HIE though a right of the Governor to approve or reject all Board members and to approve or reject any change to the bylaws pertaining to the mission of the organization, the nomination and election of directors, transparency, and conflicts of interest. These powers would undermine the integrity of the multi-stakeholder collaborative process by granting one stakeholder a dominant position over all others. A true public-private partnership can only exist when neither partner dominates the relationship. Section 6.2, Clinical and Technical Principles, pp. 68-69 Section 6.5, Statewide Core and Value-Added Services, pp. 83, 86 This comment relates to both of the sections listed above. On July 13, 2010, the NC HIE Board approved several clinical and technical principles to guide decision making for the design, development, deployment and operation of services to support the exchange of health information in North Carolina. First among the clinical principles was that the HIE solution must be consumer-centered (p. 68). This principle is further explained as follows: A critical element toward improving health is an engaged consumer who has the means, information, opportunity and the know how to better manage their own health and lifestyle choices. Consumers and authorized caregivers should be considered the primary beneficiaries of HIE services and meaningful use of HIT, and the design should be made patient-centric whenever possible. (p. 68) Another of the clinical principles adopted by the Board was that the HIE should be designed to maximize value for all participants (principle 5, p. 69). This principle goes on to state that value will come in the form of improved outcomes, increased efficiency, and increased patient and provider satisfaction (p.69). The Clinical and Technical Operations Workgroup identified a list of candidate services to be offered as hosted shared services, including a consumer empowerment service to facilitate effective coordination of care (HIE Service 2.6, Consumer Empowerment, p. 83). This service would consist of the use of a personal health record (PHR) to send a clinical summary of an office visit or a reminder for preventive or follow-up care to the patient/caregiver, as well as to provide advance directives to requesting providers (HIE Service 2.6, Consumer Empowerment, p. 83). After assessment of all of the candidate services based on several criteria, the Workgroup decided not to include the Consumer

		Empowerment service in either Phase 1 or Phase 2 of the HIE (p. 86). While we appreciate the difficulty of the Workgroup's task and its efforts in applying reasonable criteria to determine the services that might be offered by the HIE, we are concerned that the end result strayed from two of the key clinical principles adopted by the Board. The lack of PHR or patient portal functionality in the NC HIE will reduce the value and attractiveness of the exchange for providers who would like to offer such functionality, and patients will not have a consumer-centric solution by which to engage in and manage their own health care. The operational plan should address this deficiency. <u>Section 7.2, Staffing Plans for Statewide HIE, p. 91</u> It is not entirely clear in this section whether the NC HIE will contract for both administrative and technical support services, which was a recommendation of the Governance Workgroup. We urge the inclusion of this recommendation in the operational plan.
8/25/10	Dr. Greg Mears, The EMS Performance Improvement Center	I would like to acknowledge and congratulate Dr. Cline's and this group's efforts associated with this document and what will be a welcome paradigm healthcare shift. My comments are associated with two often overlooked but critical components of healthcare: • Regionalized Systems of Care for time dependent illness and injury (Trauma, STEMI, Stroke, Cardiac Arrest, Shock, Pediatrics, Burns, etc.). • The need to recognize, incorporate, and integrate Emergency Medical Services (EMS) into this HIE infrastucture. As the delivery of healthcare along with its health information exchange develop and evolve, we all agree that integration and regionalization will be enhanced. For the healthcare associated with a single event across multiple healthcare providers to be coordinated and effective, the ability to integrate EMS patient care and transport into each patients continuum of care will be critical. With the need for air medical and specialty transport capabilities to meet the time dependent care needs for these patients, EMS is a critical component to be integrated into this Health Information Exchange methodology. North Carolina is one of only 4 states which collect and maintain an electronic medical records system for EMS inclusive of 100% of the EMS Agencies and events. This information is available in electronic form locally almost immediately and within the state PreHospital Medical Information System (PreMIS) within 24 hours of the event. In most hospitals one-third of their hospital admissions arrive by EMS. For emergent issues (trauma,

		STEMI, Stroke, Cardiac Arrest) the admission rate from EMS transport is between 60 and 100%. It is a normal occurrence for a patient to be transported by one EMS Agency from the scene of a emergent event to a local community hospital emergency department for stabilization. A second EMS Agency then transfers the patient from the community hospital to a tertiary care center. The patient has touched four separate and distinct healthcare providers (Qualified Organizations) during their episode of care. Based on these points please consider making adjustments to this document as follows: 1. Please include EMS in this process even if EMS is not eligible for federal funds. EMS is critical to the future of healthcare. 2. Please include EMS as a Qualified Organization which should be participating in HIE (with or without funding). 3. PreMIS is not a surveillance system. It is an EMS electronic medical records system which is also used for surveillance. 4. Please include the concepts of Regionalized Systems of Care in this proposal and any resulting HIE use cases. Without federal funding, EMS is currently working on several initiatives: one with a large NC hospital group and another to make copies of EMS patient care reports retrievable by hospitals from the PreMIS System. Both of these initiatives are an unfunded attempt for EMS to participate in the HIE and meaningful use requirements. North Carolina is seen as a leader in healthcare and in Emergency Medical Services. Please allow EMS to have a seat at this table.
8/25/10	Troy Trygstad, Community Care of NC	Page 28 North Carolina has demonstrated leadership in HIT adoption gains. One measure of the increase in e-prescribing adoption is the percentage of physicians who route their prescriptions electronically. The percentages of North Carolina providers routing e-prescribing at year end were: 9 percent in 2007, 23 percent in 2008; and 24 percent in 2009.6 = The Figure below represents the number and type of interactions between practices and e-prescribing facilitators participating in the BCBS/CCNC/NC Medicaid e-prescribing adoption program (July 2008-present). It demonstrates the depth and intensity with which North Carolina is able to deploy HIT centric initiatives statewide and across stakeholders. This HIT adoption program as acted as the precursor to the

Regional Extension Center effort which greatly expands the scope and scale of HIT adoption.

Figure 6. Interactions between Practices and e-Prescribing Facilitators in the North Carolina e-Prescribing Adoption Initiative Sponsored by BCBSNC/CCNC/NCDMA

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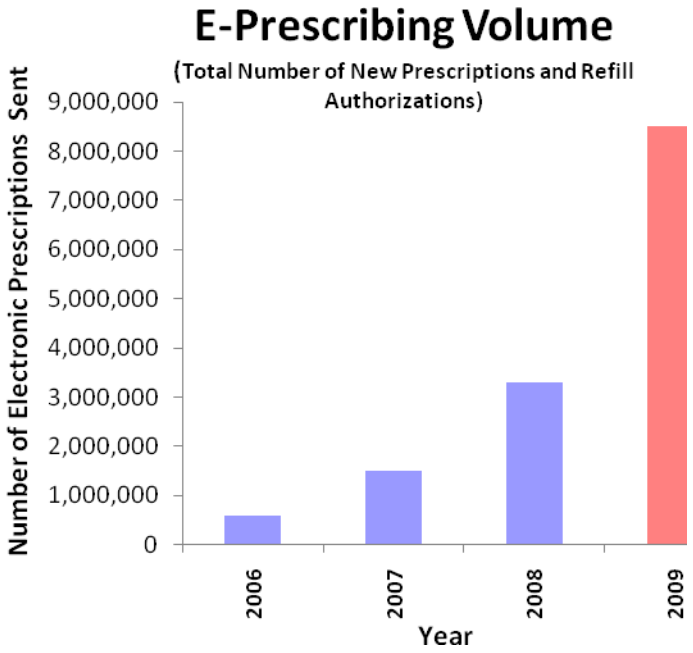
Routing of Scripts

According to data compiled by Surescripts, there were over 9 million electronic prescriptions sent in North Carolina in 2009.

Figure 7. E-prescribing Volume



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Informatics Center applications include:

Case Management Information System (CMIS). CMIS is a user-built, patient-centric, electronic record of care management activities used by CCNC care managers since 2001, with over 1,000 active users statewide. CMIS contains demographic data and claims data on over 2 million Medicaid recipients, of whom approximately 970,000 are currently enrolled with a practice in a CCNC network. CMIS also contains enrollment, eligibility and case management services for HealthNet projects across the state,

which are regional collaboratives for the care of the uninsured, currently serving 12,500 enrolled individuals. Patients enrolled in Medicaid, Health Choice and HealthNet all reap the benefits of the continuity of care provided by CMIS, which maintains a health record and single care plan that stays with the patient as he or she moves from one area of the state to another, or across eligibility programs. CMIS contains standardized health assessment and screening tools, disease management and health coaching modules, and workflow management features.

Pharmacy Home. The Pharmacy Home Project was created to address the need for aggregating information on drug use and translating it to the network pharmacist, case manager and primary care provider in a manner best suiting their care delivery needs. To accomplish this charge, the system was set up to provide both: 1) a patient level profile and medication history for point-of-care activities as well as 2) a population-based reports system to identify patients that may benefit from pharmaceutical care delivery via pharmacists, case managers and PCPs in the medical home. The Pharmacy Home drug use information database is used both prospectively (for identification of care gaps and problem alerts, targeting of at-risk patients, and development of the pharmaceutical care plan) and retrospectively (for continuous quality improvement and program evaluation).

Provider Portal? QMAF? Reports Site?

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Physicians Use of E-Prescribing Tools

One measure of the increase in e-prescribing adoption is the percentage of physicians who route their prescriptions electronically. The percentages of North Carolina providers routing e-prescribing at year end were: 9 percent in 2007, 23 percent in 2008; and 24 percent in 2009.11

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Activity	Current State (Aug 2010)	Goal (Aug 2011)	Goal (Aug 2012)	Goal (Aug 2013)
Physicians Routing of E-prescribing	24%	35%	45%	60%
Routing of Eligible Scripts	~25%	30?%	40?%	60%
Pharmacy Access	96%	97%	98%	99%

8/25/10	Dr. Sam Cykert, Area Health Education Centers	Overall, the plan is well written and meets the spirit and intent of the technical work groups and the approved policies of the NC HIE Board. The "Background" and "Approach to Statewide HIE Sections" are simultaneously informative and effective. The plan presented has the appropriate specifics when we have determined them and clearly outlines areas that need development in an orderly sequence. The following bullet points include requests for fact corrections and clarification: • Section 3.3a, pg 18, 1st full paragraph – The NC REC has already hired 27 well trained personnel

		to work on EHR implementation and Meaningful Use across the state. Fifteen to 20 new hires remain. It's important for ONC to know that we are already staffed up on the ground. Also note that our tracking tool has been built and over 1000 providers have already been submitted and entered into this web-based system. • Section 3.3a, pg 18, para 3 – ONC does not like the term "preferred vendor". They now are using the vocabulary "REC supported vendors". • Section 3.3h, pg 45, para 3 – The statement on the public health information system is "intended to rollout in late 2008". 2008 has passed. We need to be more definitive – has the system been rolled out or not. If a partial rollout has occurred, we can just say something like, "rollout has occurred in over half of the state's X health departments and the remainder of the rollout is ongoing" • Section 8.5, pg 101, full para 4, Pathway 2 – The concept provider by provider is not defined. If we mean that a patient may exclude records from every individual provider in every specialty and every category, there is a huge amount of granularity in patients exclusionary rights almost to the point of HIE chaos. This degree of granularity almost eliminates the business case for small (5 or less providers) practices to participate (1/3 of NC practices and > 1/3 or rural, primary care practices). My suggestion is that providers who can be excluded be more narrowly defined. • Section 8.5, pg 101, last para – I think that we should specifically say that individual patient consent will not be required for aggregation of de-identified data. • With patient-centeredness serving as a major focus, consumer access and patient portals should be mentioned somehow as a future goal to be supported by HIE. Would allude to this somewhere in the Technical section (around section 6.5, pg 85) and the Access section (around section 7.6a, pg 105) In conclusion, this operational plan is strong and needs only mild modification.
8/25/10	Larry Forrister	General: On pages 30 and 54, 58 county public health labs are enumerated, but no mention of SLPH. In fact SLPH is not singled out except in one place under PH notifiable results. General: Pg. 63. States that NC HIE must develop in way consistent with public health and public policy, but these are not defined. The State has a non-delegable role as steward that must be preserved and must protect state assets. What is this role and what are the assets. Reference is made to articles of incorporation provisions that cannot be altered. Unfortunately the articles are not included in this draft (placeholder). Reviewing these provisions might provide some clarity. General: Pg 65 state that on consumer advisory council, representatives do not have financial stake in healthcare system. Clarify to mean stake in financial gain? as consumers certainly have a very real financial stake in the cost and provision of health care services.

		General: I know that there are plans to update the strategic plan but regarding the Technical Infrastructure: no where is there a principle reference back to strategic plan that the NC HIE is a federated model without a central data repository. See reference below from strategic plan (pg 41): 3 Deployment Topology: Federated Architecture In support of community-based health information exchange, as well as data security and privacy concerns, one preferred deployment topology for the NC HIE infrastructure is federated. In a federated architecture, there is no centralized database where all patients' medical data would be stored. Instead, in the federated approach, each healthcare organization has ***ownership*** and ***local control*** of their patient's healthcare data (the data is stored locally). General: For value-added shared services, proposal from clinical/operations group is to have immunization (pg 82/3) from provider EHR to/NCIR and the routing of reportable lab results (pg 84) from provider to public health go through HIE rather than point-to-point. Has this been fully vetted with providers and within PH/DHHS as way to go. Could there be a choice of point-to-point and HIE routing for those providers who can't do point-to-point to achieve MU? Assume this will be proposed direction for Phase 2 shared services Disease Surveillance from provider EHR to NC EDSS (pg 84). General: Did not see the 85 public health departments specifically enumerated as a provider type anywhere, nor mention and citation of their crucial role in services for the Medicaid population or underserved/uninsured constituents. (example see page 11 where entities are enumerated)
8/25/10	Dr. Warren Newton, UNC School of Medicine	per Chris Singh Colleagues, I write in response to the request for comments on the HIE operational plan. As a member of the board, I have listened to the discussions, reviewed the Powerpoints that have been given and have briefly looked at the overall operational plan, although I have not read every page. Overall, a great deal of work has gone into this and many fundamental decisions have been made about how we are going to organize HIE in NC. At the same time, I think there are important issues that need to be addressed either in the final operational plan or the first month of the operational process. What follows are divided into vision, architecture and overall: 1. Vision - I am comfortable with the vision statement as it stands but I would like to propose that we include a phrase that assesses and underscores the open table and inclusiveness that is characteristic of NC programs. I don't believe we will reach our potential unless we include this as part of our vision. As it stands now, it will often feel like it is top down. 2. Architecture - I believe we need to build in an attempt to identify practices as another element of

		the architecture - distinct from individual providers and from organizational units. It is clear that, moving forward, it is practices--individual smaller units--that will become the intermediary for medical care in the outpatient setting. This is a change in thinking from our traditional approach which tracks individual providers (a la Sheps workforce database) and quality (measured at the level of the individual physician). There is increasing recognition that it is practices that have office systems and these office systems are critical for cost control and quality. We need to build this into the architecture. Indeed, the success of CCNC is in part due to its ability through Medicaid enrollment to identify practices as opposed to providers. In our work with NCHQA, we have appreciated how difficult it is to identify practices but if any state can do it, NC can do it. Without having information at the level of the practice, it will seriously weaken the overall ability to achieve the desired outcomes. 3. I continue to be concerned about the limitations on the "opt out" structure. Small changes in this process may be necessary for political compromise but small changes will greatly impact the benefit/cost ratio at the level of individual physicians. I believe we are to sate an "opt out" approach and see what we can get. I don't think it's useful to concede at the beginning before the political process starts. 4. Who owns the data? A major issue with IPIP and NCHQA as well as CCNC is ownership and control of data. Insurers have a great deal of data about individual patients but lack individual quality metrics. Doctors have felt very concerned about ownership of data and the use of data in a "gotcha" approach. We specifically need to address this issue as a part of our planning process. At the very least, there needs to be a commitment to total transparency including all insurance company data about individuals and adherence and the like, as has been modeled by CCNC. We must not paper over this issue. It is fundamental and huge and we need to address it. We are well organized to be able to address it. 5. Where are PCMH and ACOs in this structure? I think there is common recognition that PCMH and ACOs are the key building blocks of health care reform. The architecture and plan does not explicitly include a strategy for how those will engage. In particular, I'm concerned that there hasn't been a focused effort to say how primary care will be particularly enhanced by this - nor how the qualifying organization/ACOs will interconnect. Perhaps, there can be some element of an intent to do this in the first part of the operational plan. Overall Comments: 1. Where will the savings come from? As currently constructed, I believe the HIE will not be of substantial utility to individual clinicians, for a number of years. There will be some ability to find out and limit duplicate testing. When I asked this question of the board, the answer was, vaguely, "well ACOs will be able to take care of that". If that's the case, then we need to make an explicit commitment to developing aggregate charges, RVUs and costs with routine definitions but we still need to make it useful for individual physicians.

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2. How will the HIE support quality improvement? The document describes CCNC and their quality infrastructure. We need to be specific about planning to include the NC Health Quality Alliance, a complimentary effort. More broadly, there needs to be recognition that our strategy for measures needs to be developed across the state. Quality improvement needs to be rapid cycle, the data systems need to be able to support this and it needs to include primary care, specialty care and hospitals. As structured, the HIE will do relatively little to support measured quality of care. This needs to be a focused area of planning over the next 2-3 months and we look forward to that process.
3. Perhaps the most important issue of all is the value ratio for individual practices. As currently structured, there will be substantial cost of this enterprise for individual practices. It's no accident that most of the presence around the table has been hospitals and given the rapidly changing organization of care this is very appropriate. It is hospitals that seem like they will have the capital to be able to intervene. But, the cost for individual practices--both direct and indirect--are substantial. Yet, the value is almost none for the first several years. There is a stick out there in the sense of Medicare beginning to subtract if people don't e-prescribe, and the like. The amounts of money are modest compared to the direct and indirect costs of this. Fundamentally, we don't want to be in a situation where we are doing this only with a stick and with little clinical benefit to practices or to patients.
4. I believe that attending to the case for individual physicians--to get engaged and want to do this--should be a first priority of the operational plan including the indirect office costs. I think we ought to consider including functionalities that will be "win-win" that will allow physicians and their offices to reduce costs. The same argument goes for hospitals - we need to explore claims processing. If indeed the experience of the North Eastern Health Information Exchange is referable in some way, there may be benefit here. In any case, we ought to look for things that will actually help practices and hospitals' bottom line.
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<td>8/25/10</td>
<td>James Murphy, Information Security Architect NC DHHS OMMISS</td>
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<table>
<tr><th>Page</th><th>Location</th><th>Recommendation</th></tr>
<tr><td>8</td><td>Top bullet under "Legal and Policy Workgroup"</td><td>Change to "...protect individual privacy and strengthen the security of health information..."</td></tr>
<tr><td>8</td><td>3rd bullet under "Clinical and Technical…"</td><td>change "...flexible and scalable…" to "…flexible, scalable and securable…"</td></tr>
<tr><td>18</td><td>3rd para from bottom</td><td>adjust to remove implication that this is a system hosted by CCNC</td></tr>
<tr><td>14</td><td>2nd para</td><td>Add text to paragraph to emphasize a technical threshold requirement; the process of terminating a Qualified Organization</td></tr>
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				must be discussed at a later date.	
		14	4th bullet at bottom	qualify bullet, e.g., "Possibly facilitate…"	
		15	3.3 Health IT and HIE Landscape	Obviously, details require attention, but this process at least should be studied.	
		73	7.3 Shared Statewide Technical Architecture	Though this may be part of future design and development, it must be clarified that the State HIE requires a clearly delineated perimeter to insure that all participants are aware of the boundaries. The HIE perimeter must not be extended within the existing operational environment of an HIO, lest the HIO be liable for imparting vulnerabilities and threats into the larger HIE. Evidence indicates that end points of networked organizations are the most vulnerable components.	
		77	Table, row 1.	Please clarify	
		79, 80	first two bullets, "Service Access Layer", "Security Services"	Replace "…trust broker…" with "…identity, authentication and authorization services…"	
		80	top bullet, "Security Services"	Change bullet to "Access Control and Identity Management Services"	
		86	Table	Effort should be made to implement phases in stages - managing expectations and seeking a robust architecture that allows for scalability and extensibility while retaining infrastructure integrity. Pursue small successes that breed confidence over the long haul, taking on too much can lead to "scope creep" and un-achievable expectations. Experience gained from the Replacement MMIS project can be invaluable.	
		87	bullet list: Privacy and Security, Encryption bullet	Please clarify	
		87	bullet list: Privacy and Security, Data Integrity bullet	Please clarify the need to have a separate hash from the included components of TLS.	
		87	bullet list: Privacy and Security, Data Integrity bullet	Identify the specific NIST or FIPS reference.	

		91	7.3 Approach for Technical Assistance to HIOs	Indicate the expectation of a technical threshold with technical and operational security practices.	
		91	7.4 Standing Operating Procedures for HIE	See Comment #7 - these bullets must be considered as factors in the discussion of the HIE technical/network perimeter	
		97-98	Table	Besides the "Value" and "Cost" bullets, I suggest adding an additional bullet addressing "Cost of Unauthorized Disclosure or Alteration". This is untested waters, but may be more costly than implied by the last three bullets on p. 98. This "Penalty Cost" may be the best justification for properly designed architecture and protection mechanisms.	
		102	8.6 "Security" - bottom paragraph	Rather than "...engender trust across all participants", I suggest "ensure protection commitments among all participants." Discussion obviously required.	
		103	bullets at bottom of page	First bullet assures human authorization of requestor, e.g., "A process for verifying the identity and permission of individuals seeking access to the system for health information exchange." Second bullet addresses the system process(es) to implement the access permissions for the individual, e.g., "A set of systems processes to enable the specific access permissions approved for the individual seeking access."	
		104	Role-based table	Re-work the terms to match the Standard - to be discussed, details can be provided at a later time.	
		105	bullets at top of page	See above.	
		105-106	"Authentication" section	Authentication is based on three primary attributes: who one is (e.g., unique identity) what one has (e.g., biometrics, smart cards, pin numbers), and what one knows (e.g., password) Single-factor authentication includes the login ID and the password - the ID validates the identity of the individual and the password lets the system know that the user ID is tied to the identity. Two or more factors include biometrics, pins, etc. It may be worth considering a two-factor authentication process for the HIE.	

		106	"Access" section	Well done for including training and sanctions for improper usage of accounts. De-provisioning - deactivating and removing accounts of departed users - is also important to include in this section.
		107	7.6.b Breach	This can be crafted to be an incentive for dynamic attention to network assessment. Also, this plays a part in the points of Comments #4 and #7, the technical threshold and clearly delimiting the perimeter of the HIE.
		108	7.6.c …(CIA)	Confidentiality and Integrity are components of protecting information, Availability is a component of controlling access. Though these three terms are ubiquitously utilized and recognized, there are many more components than these three - more detail can be provided, if necessary.
		131-133	Risk Assessment table	Label the table to indicate Planning and Initiation. Risks must be evaluated for the procurement (RFP and proposal evaluation) process, and the technical design and development processes. Subsequently, the pre-operational system will need a final assessment for controls of threats and vulnerabilities.
		134	Technical/Clinical table	These must be included in preliminary technical design plans before an RFP can be distributed - RFP requirements must reflect the expected plans.
		136	Legal/Policy table	Security policies and plans must be developed in conjunction with the technical/architectural design phases
8/25/10	Jack W. Walker, PhD., NC State Health Plan	In Section 3.1 and others of the NC HIE Operational Plan draft, the NC Health Information Exchange (NC HIE) states the desire for flexibility through the use of multiple "qualified organizations" with demonstrated expertise and capability to feed information into the statewide HTE. We agree that use of multiple "qualified organizations" will facilitate the work of the NC HIE by drawing on the accomplishments and work in progress of the various stakeholders across the state, including Plan initiatives through ActiveHealth Management. The Plan is excited about the opportunities that will be available through ActiveHealth Management's tools and hopes that we may work in partnership with the HIE team to promote the concepts of both the overall HIE project as well as the Plan's initiatives.		
8/25/10	Marci Ann Keiser, Central Regional Hospital	Reference: Considerations in Determining Consent Framework Please note that conservative estimates of at least 50% of our mental health patients at Central Regional Hospital (CRH) have comorbid substance abuse problems covered by 42CFR.		

		CRH is one of the two hospitals referenced for the initial deployment of VistA under the State Agency Adoption of EHRs.
8/25/10	Reda Chouffani, Biz Technology Solutions, Inc.	As described in Page 179 about 29% of the state's physicians below to a small practice of 1-5 physicians. And in reviewing several of these smaller practices, they are the ones that face the most difficulty in adopting EHR. This can be due to lack of resources and financial restrain. Also, there are a number of these organizations that might have already implemented an EHR, and realize that their product may not be certifiable (Hybrid EHR) or due to lack of vendor commitment to MU. My question is: Would a State HIE mandate the certified EHR in order to accept connectivity? Would there be commercial options that would act as proxy for small physician practices that are still interested in receiving medical information about their patients even if they do not have a Certified EHR implemented. In the section titled: Statewide HIE Services, it states that additional services would be available for non standards-compliant EHR system. Would the fees for these services covered by the physician? Under the Value Add Services in Page 81, there are several services that will improve efficiency for physicians and over clinical workflow. These services are listed as services to be offered as hosted shared services. My question is: Does participation in these services require subscription in the Core services? On page 83, there is a mention of Provider EHRs would send immunization records to the HIE for transmittal to the registry. Has the NCIR defined a timeline when they would accept Immunization records via HL7 to support this value add function?
8/25/10	Richard Franck IBM Global Business Services Healthcare and Life Sciences	page 15: a “provider portal” is not likely to enable a provider to meet meaningful use requirements. A web-based EHR could be offered as a “value add” service of the state HIE that could assist a provider in meeting meaningful use. However, this paragraph combines the notion of “unaffiliated with or unable to participate in a Qualified Organization” with not having an EHR. The way to leave no provider behind is to allow individual providers (or small provider groups) to be a “Qualified Organization” and connect their EHR directly to the state HIE. page 75: “For example, if there are existing or additional patient indexes, federating a query against a statewide MPI and other indexes is necessary to allow for ongoing local or regional innovation. A statewide patient identity service would include querying for patient identities against both indexes.” Understanding that this is only an example, but it may not be a very good one – it is probably better to synchronize a statewide patient index when updates are made (relatively infrequent) rather than when a query is made (more frequent).

p. 79, p. 80, refers to “the trust broker”, but this is not defined. I recognize this phrase from other Manatt presentations and documents, but it is poorly defined in those as well, and should be removed from this document in favor of a more clear definition of “Security Services”.

p. 79: the statement “The Service Access Layer is based on the NHIN messaging platform standard as approved by HHS” should be clarified. Is “based on” meant to imply that the only allowed messaging connections will follow a standard that is similar to the NHIN messaging platform? The NHIN messaging platform was intended **only** for connections between HIEs. The NHIN working groups recognized that the protocols and standards selected for the messaging platform were too stringent for the “last mile” interfaces from typical EHRs in provider offices and from hospital information systems.

Adoption of the NHIN messaging platform standard would limit access to the core services to entities that implement that standard today – which is almost no one. The Service Access Layer should accommodate protocols used by typical end systems today (such as XDS document sharing and HL7 version 2) as long as the security requirements of the state HIE can be met. There are a variety of ways that these security requirements can be met with those existing systems; for example, use of Virtual Private Networks for transport security, and the use of HTTP Basic Authentication for user authentication.

p. 80: the definition of security services could be improved. Key capabilities of the security services should include:

- participating entity (organization) provisioning and de-provisioning
- participating user (providers, nurses, provider office staff, medical technicians, etc., as well as patients) provisioning and de-provisioning, including information about the user's role
- authentication of users
- management and enforcement of access consent polices (computer-processable statements of who is allowed to access patient records under what conditions). The security services should have the ability to maintain and enforce policies that apply to specific patients, policies that apply to data created by a specific organization, policies that apply to certain types of data, and policies that apply throughout the HIE. The access consent mechanism must have the ability to enforce these policies in a priority order determined by the NC HIE based on federal and state regulations and NC HIE policy decisions.
- auditing transactions, and providing reports on the transaction audit log to authorized users
- verification of digital signatures and management of digital certificates
- the ability to unambiguously link a set of patient records to a specific user (with a user role of “patient”) to grant that user access to their own records but not the records of others

p. 80: “The default approach is to keep records in their current location with the possible exception of limited demographic data.” This statement is not appropriate in the strategic plan, as it may be determined

		during implementation that this is not the best approach for a majority of participants. p. 80: The second and third capabilities described under the "Person/Patient matching service" would more accurately be described as a "data query, storage and retrieval service". I think it confuses the issue to lump this together with the patient matching service, since there are many off-the-shelf products (MPI products) that perform the patient matching capability, but not the query/retrieval capability. At the very least, the name of the service should be changed to indicate that it is broader than "patient matching" but includes finding, retrieving, and optionally storing patient data. p. 80: there may be value in combining the Master Facilities service and the Master Clinician service, to make it clear that the service can and should understand the relationships between facilities and clinicians. (This is important, for example, in measuring outcomes against quality goals at a practice or organization level.) Many off-the-shelf products provide these capabilities in a single product. In addition, calling this a "service" instead of an "index" would emphasize the notion that these are dynamic registries that can be updated and queried by entities in the HIE. p. 82, 86: I strongly agree with the assessment that Value-added services 2.2 and 2.3 "could be more effectively facilitated through existing exchange services" -- namely, health insurance clearinghouses. p. 83: the description of value-added service 2.5 (which I think is erroneously duplicated in 2.4) includes both the translation of clinical documents (which I think should be the intent) and the exchange of those documents. The ability to exchange clinical documents should be a core service, and is described as such (See my earlier comment on the distinction between the "Person/Patient matching service" and a "data query, storage and retrieval service".) Item 2.4 should be deleted, and the description of item 2.5 should be narrowed to refer only to the transformation capability. p. 83: I fully agree with the use cases described in 2.6 "Consumer Empowerment", but this item does not describe a "service". Rather, these capabilities are supported by a variety of the core services: patient identity matching, data storage and retrieval, and security services. It would be more accurate to include the ability to support these use cases as a requirement of the core services (as some of my earlier comments have done). As such, I disagree with the assessment (table on p. 86) that these capabilities should not be part of the HIE. It would be appropriate to describe the ability to offer a PHR that is connected to the NC HIE as a value-added service, and this would be a valuable offering. p. 84: the description of item 3.4 "Disease surveillance reporting to local public health and state agencies" refers only to providers submitting data to a public health agency. The value-add that the HIE provides in this scenario is to automatically submit data to the public health entity from a single source, relieving the

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<td>provider of the burden of doing so – as long as the provider is capturing that data and submitting it to the HIE as part of their regular provision of care (which should be the goal). The description of this item should be reworded to emphasize the efficiency that could be gained by having a “disease surveillance service” as a value-added service of the HIE, by centralizing that function and removing the burden on each provider of maintaining these interfaces to the public health agency. (This same service could also support the reporting of notifiable conditions and lab results to a state or local public health agency.)

p. 85: the description of item 5.1 “Clinical Decision Support” should emphasize that a more robust set of clinical recommendations can be provided when the Clinical Decision Support service has access to the entire patient record from all sources (ambulatory, hospital, medication history, lab results, Medicaid, immunization registry, etc.), as opposed to the more narrow scope of patient records that are typically available to an ambulatory EHR or hospital CIS.

p. 88: the bulleted list of core services capabilities is not consistent with the definitions of the core services on pages 79-80. Please refer to my earlier comments on the definitions and capabilities of those services.

p. 89: Figure 16 does not adequately capture the relationships of the core services to the high priority use transactions. I think it would be more accurate to say that all of the core services (including the Service Access Layer, though excluding the NHIN gateway) are involved in the exchange of lab results and summary care records. And the table on p. 86 indicates that the NC HIE does not intend to provide an e-prescribing service, so those transactions would continue as today – between the provider EHR (or other e-prescribing application) and the pharmacy network. This figure is neither accurate nor necessary.</td>
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<tr>
<td>8/25/10</td>
<td>Robin Wright</td>
<td>1. Addition to Section 6.5, pages 78 and 90, Statewide Core and Value-Added Services (number 6 NC HIE value added service as a Phase 2 item on pages 85 and 86): develop a NC HIE patient portal. As illustrated by the table below, a simple electronic health record view-only portal provides concrete value to health care providers and their patients:
<table>
<tr><th>NC HIE Ops Plan (Section/Page/Paragraph)</th><th>Value to Providers (NC HIE Subscribers)</th><th>Value to Consumers</th></tr>
<tr><td>6.2/68/Clinical Principle 1…consumer centered

6.2/69/Technical Principle 3…support individual health…</td><td>Means to provide 9.4 million patients with access to their EMR</td><td>Means for 9.4 million consumers to access their medical information, to manage health, correct data, etc.</td></tr>
<tr><td>6.2/68/Clinical Principle 5…maximum value to all</td><td>Developing a single portal is cost-effective and makes this service available to</td><td>Free access to medical information benefits all NC citizens (note: consumers</td></tr>
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			10,024 small subscribers (note: providers may be eligible for an incentive payment)	are not eligible for an incentive payment)
		6.2/69/Technical Principle 5…*system that is consistent, repeatable and re-usable…* 8.3/87/…*consumer trust is paramount to engender public support for the Statewide HIE…*	Potentially avoids the duplication of effort to create 18,573 different NC patient portals (page 113)	A familiar system with an open and transparent process engenders trust (76% of adults reported they looked online for health information (Harris Poll conducted via telephone, 8/10/2010)
		8.2/93/Consent Approach…*patients want meaningful control, providers want minimal administrative burden and cost*	Potentially minimizes the need for 18,573 practices to provide medical record paper copies to 9.5 million consumers (page 113)	Online access provides meaningful control (potential for patients to document consent, correcting errors, etc.)
		A detailed cost-benefit analysis will provide the information needed to determine if including a patient portal is feasible. The analysis should include the possibility of future benefits. For instance, once established, the NC EHR patient portal could be used for other online services such as; personal health record, clinical trial recruitment, patient support groups, grief counseling, personal or provider health reminders, appointments, etc. Creating a NC HIE patient portal would allow NC HIE to offer equal value to large or small provider practices and their North Carolina patients. 2. Addition to Section 5.4, page 78: ***develop a process for handling spontaneous feedback from the public to the NC HIE Board***. This process should be easy for the public to access and use, and be independent of the formality of a NC HIE Board meeting or a NC HIE committee. Continually tracking public comments, suggestions, compliments, complaints and the responses provides a basis for improving NC HIE technology, processes, and/or services.		
8/25/10	Paul Adkison, IQMax Inc.	1. Our understanding of the Qualified Organization model is that participation as a QO will be open to many different types of organizations, such as IDNs, hospitals, lab facilities, as well as Regional HIEs. It is understood that there will be fees associated with connecting to the State HIE in the form of connectivity and membership fees. As a participant in a Regional HIE (Carolina Health Information Exchange) our concern is that many large organizations will choose to connect directly to the state HIE and bypass the regional HIEs. This is a concern for a number of reasons, specifically: a. Lack of participation in regional HIEs by larger organizations will negatively impact the sustainability of those regional HIEs, since membership fees will not be paid to the		

		regional HIEs but rather to the state. b. The State HIE intends to collect connection and membership fees from regional HIEs; if the sustainability if those regional HIEs are compromised due to lack of participation, there will not be any fees to collect from the regional HIEs, thus threatening the sustainability of the state HIE. c. Lack of participation in regional HIEs by large organizations may negatively impact the availability of patient data in the regional HIEs, since this data will be shared directly with the state instead of at the local level. It is unclear when and how this data will be available to the regional HIEs, whose members will require it for treatment purposes. d. Lack of patient data from large organizations at the regional level may impact participation by smaller organizations. Without participation the regional HIEs will cease to exist, and many smaller healthcare entities who do not have the ability or finances to become a Qualified Organization will be left without a means of participating in health information exchange. e. The vast majority of healthcare services are utilized by those in the local community. Without full support of, and participation in, data exchange at the local level, the utility of any system will be diminished. Localized exchange of data should be supported by and facilitated by the state. 2. Currently, there are no board seats reserved for the regional HIEs, nor for consumers. We feel that the board would not be able to appropriately represent all the primary stakeholders without formal representation of these two groups and recommend creating seats to represent these two stakeholder groups. This will help ensure that the local and regional efforts are accounted for in developing the statewide system, and that the voices of consumers, whose data is being exchanged, will be heard.
8/25/10	Mark Bell, NC Hospital Association	Correction, p. 19, two instances: "North Carolina Healthcare Information Exchange (NCHEX)" is incorrect. The proper name is "North Carolina Healthcare Exchange (NCHEX)" Correction, p. 20, second paragraph. Replace with: "NCHEX allows caregivers to access HIE data via their native EHR interface or a secure Web browser to view summary and detailed information about a patient over time and across providers through a Virtual Single Patient Record viewer, including:" Correction, p. 39-40: replace entire NCHESS description with the following: North Carolina Hospital Emergency Surveillance System (NCHESS) NCHESS was developed in 2004 by the North Carolina Hospital Association (NCHA) and the NC Department of Public Health using funding provided by the U.S. Department of Homeland Security through the Centers for Disease Control. NCHESS is a statewide clinical data surveillance program that captures real-time clinical data from

		hospital information systems and analyzes that data to quickly and accurately identify public health emergencies at specific hospitals, in certain geographic locations, or across the state. The NCHESS Emergency Department Data Interface (EDDI) is in place at 114 hospital emergency departments statewide and collects 23 discrete data elements and provides syndromic surveillance, situational awareness, and clinical information of public health interest. In addition to the surveillance function, NCHESS Investigative Monitoring Capability (IMC) is in place at 45 of 114 hospitals, with 11 more capable of enabling this feature. Utilizing technology created by Thomson-Reuters, the IMC monitors all hospital clinical data, including ED data, in real time for patterns suggestive of public health threats and alerts hospital and public health officials accordingly. The IMC provides epidemiologists at DPH and at hospitals with the ability to electronically "reach back" into hospital information systems to access electronic data on individual patients to further investigate specific public health concerns. Over its lifespan, NCHESS has collected over 19 million unique patient visits and over 115 million individual records. The data from 114 NCHESS emergency departments comprises 93% of the data monitored by NC DETECT for public health surveillance in North Carolina. This represents approximately 25% of all the hospital data contributed to the CDC's BioSense surveillance system. We anticipate adding approximately 9 new EDs to NCHESS by the end of 2011. Comment: Regarding financing in Section 9, NCHA supports an equitable approach to financing the NC HIE that also promotes access for stakeholders who provide or manage the care of vulnerable populations, such as Community Care of North Carolina, free clinics and safety net providers. Comment: Regarding consent policies in Section 8, NCHA supports an opt-out consent model at the provider level and is concerned that requiring Qualified Organizations to adopt a more complicated consent model based on restricting access to patient data on a selected-provider basis will be too complicated to maintain and will lead to inadvertent restrictions or disclosures of patient data. We would rather have the clinical and provider details regarding an episode of care unavailable on the HIE (except to the submitting provider and where required by law) and give others on the HIE access to summary information such as the date and time of the encounter, as well as the general category of the encounter, such as Hospital, Emergency Department, Urgent Care or Physician Practice. This method will enable better detection of waste, fraud and abuse in the healthcare deliver system and maintain consumer privacy without placing a technological burden on the participating Qualified Organizations. Comment: Regarding core services, value-added service and minimum data sets required of Qualified Organizations to participate on the NC HIE, we encourage the adoption of a minimum data set and interoperability standards that are consistent with NHIN requirements as the basis for being allowed to join the NC HIE. We are concerned that additional technical requirements will force existing HIEs to

		reengineer their systems at great expense and will delay other providers or groups of providers to join a Qualified Organization or connect directly to the NC HIE. We suggest the NC HIE consider tiered levels of participation on the NC HIE to accommodate NHIN-compliant connectivity on one level, and another level of participation for those Qualified Organizations or providers whose IT infrastructure can support advanced or value-added services. A tiered approach to technical capabilities could be paired with an appropriate financing model to help sustain the NC HIE while maximizing participation.
8/5/10	Melanie Phelps, NC Medical Society	Overall, we are pleased with the general direction outlined in the draft operational plan. We particularly like the qualified organization approach in Section 3 as it provides physicians and other health care providers with more options for connecting to the state HIE. That said, and so as not to unnecessarily delay or increase the cost of implementation, we would like to see that potential qualified organizations that meet minimum NHIN standards have some flexibility in meeting NC HIE standards that exceed those of the NHIN. Our primary concern with regard to the operational plan relates to patient consent. We understand that the no-consent approach even for treatment purposes is less politically feasible in an era of more widespread sharing of health information electronically. However, if the overarching purpose of the NC HIE is to improve the quality, cost-effectiveness, and efficiency of health care, then the best approach (assuming appropriate standards and safeguards are in effect for those handling protected health information) is that consent would not be needed for treatment purposes—everyone and all their health information would be in the HIE (except the federally-assisted alcohol and drug abuse treatment facilities or programs, which have disclosure restrictions under federal law). The further we get from this approach, the further the NC HIE will be from maximizing its quality, cost-effectiveness, and efficiency potential. Again, we understand that the no-consent approach may not be politically viable in an environment of electronic health information exchange where the stakes are higher with more people having access to that information. With this in mind, we can support an opt-out approach. That said, we have serious reservations about allowing for a partial opt-out whether it is giving patients the ability to prohibit specific providers from disclosing information into the HIE or to restrict access to certain information. Opt-out, whether partial or complete, will require physicians to obtain information through methods that are currently used and are widely viewed to be inefficient and burdensome (getting the information from the patient, who may or may not have or wish to provide that information, or directly from the other providers, which takes staff time and effort at both ends). The partial opt-out by provider, however, raises an additional concern if prohibited information is later incorporated or co-mingled into the record maintained by another physician (who is not prohibited by the patient from disclosing to the HIE) and that information subsequently gets disclosed into the HIE. While the patient consent issue has received significant attention, we think that further discussion is warranted. We also suggest that we not commit to a particular opt-out approach at this time and recommend that subsection 8.5, page 101, under **Consent for Treatment Purposes** be amended as follows:

		The NC HIE will pursue an Opt-Out model for the exchange of patient health information through the NC HIE for treatment purposes that includes all available data from all provider types (i.e., a change in law that would allow data from mental health providers, nursing homes, adult care homes, and home health agencies to be included. ~~*and that allows consumers to restrict disclosure of data to the exchange on a provider-by-provider basis. In cases where information is filtered out, records accessed by treating providers would contain a notification that the record may not be complete.*~~ *The NC HIE will conduct further research on the pros and cons and feasibility of allowing more granular patient control over what information is disclosed to or access through the exchange, taking into account evolving technology and with an eye toward the impact that more granular patient control may have on both provider and patient participation in the HIE.* With regard to financing, we would like the principles under subsection 9.6 to embrace equitable cost sharing so that the smaller providers are not burdened with paying the same amount as larger, better capitalized, providers. One way to address this would be to adding the underlined language to the fourth bullet on page 117 as follows: *Be paid for by all participants and beneficiaries of health information exchange, including the state, in a fair and equitable manner*
8/26/10	Maureen O'Connor, BCBSNC	I reviewed the entire Draft Operational Plan but focused most of my attention on the first 60 pages, the last 20 pages and the Finance section. I think you, Steve, Alan, and the Manatt team, have done a fabulous job pulling together a comprehensive plan in a very compressed time frame. Congratulations! I know it will be a difficult task to integrate all the comments you receive. I have only three substantive comments and they relate to the Finance section of the document. On page 9 we reference the fact that one of the charges of the Finance Workgroup is to develop a budget for the initial implementation of the Statewide HIE. In the Finance section of the document we give some high-level estimates of the cost of the annual operating budget ($2M-$5.5M), but we do not address implementation costs. This seems to be a gap, unless I have missed something. On page 113, I would suggest adding a sentence at the end of the last paragraph on the page to state: "It is unclear whether those surveyed are using a common definition of an EHR system." In our discussions about whether the survey conducted by the NC Academy of Family Physicians on EHR adoption was reliable data, we noted that physicians might have very different views about what constitutes an EHR system. Some might construe their practice management system as an EHR System. I think it's important to note that these assumptions around current adoption rates may be high. Finally, on page 115 we describe the anticipated adoption rates by hospital systems, stand-alone hospitals and provider offices. It may be helpful to explain whether "provider offices" includes physicians associated with (salaried) large hospital systems. The 14% assumed rate of connectivity may be

		understated if we have removed physicians who are part of hospital systems (like Novant, CHS, Duke, etc.).
8/26/10	Dr. Eugene Leung, CMIO, Rex Healthcare	Correction for Section 2.3: End of the second paragraph, I believe the Stage 2 criteria will be out at the end of 2011 (Not 2010 as stated in the document) In figure 4 (p.12) you describe 2 approaches to HIE, either based on organization or by territory. I support your decision to favor the organization based approach. This approach leverages the fact that a local organization is more likely to provide good governance of an individual local practice from a data perspective compared with a territorial governing body that the individual practice may or may not have had a relationship with before. Furthermore, often there are multiple large competing organizations within a territory. Assigning one of these organizations or even an "independent" organization may lead to distrust of how the data is used and may lead to poor participation/cooperation. On p14, you enumerate the benefits of participation in an HIE. I have more discussion about HIE's ability to facilitate the reporting of transmissable diseases, immunizations and possibly participate in syndromic surveillance. I think this will help illuminate the benefit that an HIE can provide practicing physicians in their day to day life. This area is covered, however, only briefly in your phrase... Facilitate access to North Carolina state government information, including possible access to Medicaid and public health data. I wonder if we could have more information about other HIEs who have tried the other models (For example, the favored "Hosted shared statewide services") and info about the pluses and minuses as well as if and why they've failed.